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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Earl M. Zergiebel

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EXAMINER

WISTERMAYER, ALEXIS M

ART UNIT

PAPER NUMBER

3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,879	Applicant(s) ZERGIEBEL, EARL M.	
	Examiner Alexis M. Wistermayer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-22 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-22 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1-14 are objected to because of the following informalities: in lines 5-6, "the head portion having driver receiving structure" should read –the head portion having a driver receiving structure--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "the slot" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-9, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Sanders et al (US PGPub 2003/0158555).

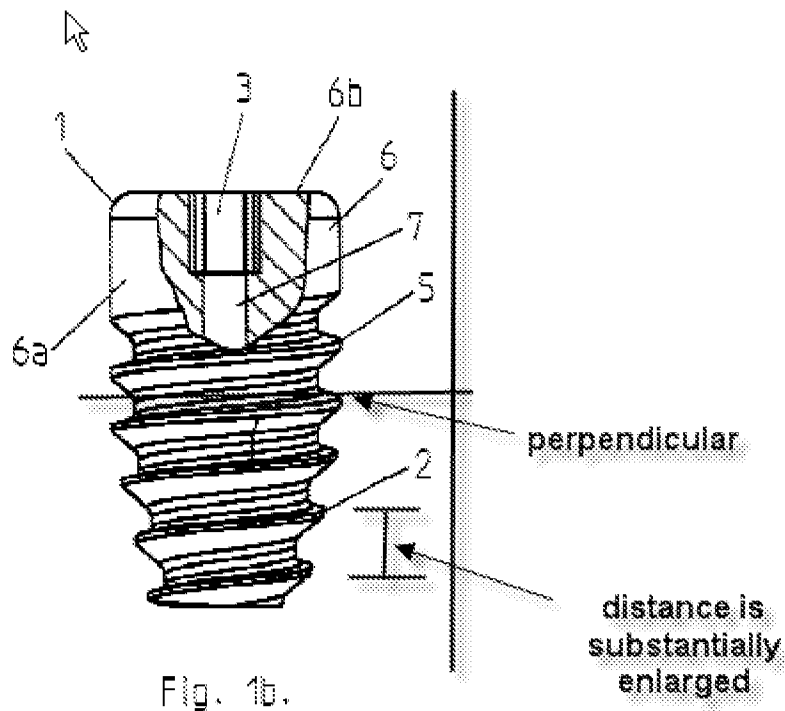
Regarding Claim 1: Sanders et al. teach an absorbable screw fastener/surgical screw system a body portion/shank having a proximal end, a distal end, the body portion/shank being threaded (Paragraph 29), and the head portion having a driver receiving structure (Paragraph 30). The diameter of the head is roughly/substantially equal to the widest diameter of the body portion/shank (Paragraph 97). Figure 2d, an alternate embodiment, shows a driver receiving structure formed in an outer radial surface thereof.

Regarding Claims 3 and 4: Sanders et al. teach a driver receiving structure that has a substantially flattened surface (Figure 1b, the top of the screw head indicated by 6b).

Regarding Claim 5: Sanders et al. teach a device where the fastener is formed of PGA/PLA and PGA (Paragraphs 37, 39, and 41).

Regarding Claim 6: Sanders et al. teach a fastener where the distal end is blunt (the very bottom of the screw shown in Figure 1c).

Regarding Claims 7 and 8: Sanders et al. teach a fastener where the land of the thread is substantially perpendicular to the longitudinal axis and where a distance of the thread is substantially enlarged (please see drawing below).



Regarding Claim 9: Sanders et al. teach a fastener which has a minimum head portion diameter of 3.5 mm and a maximum head portion diameter of 4.5 mm (Paragraph 107).

Regarding Claim 12: Sanders et al. teach a fastener including a lumen/central bore extending through an entire length thereof (Figure 1c Element 7).

Regarding Claim 13: Sanders et al. teach a fastener with a body portion having a circular cross-section (Figure 1a Element 2).

Claims 15, 16, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotfried (US Pat 5429641).

Regarding Claim 15: Gotfried teaches an instrument comprising: a distal portion having an elongated outer tube/shaft (Figure 11 Element 47), a proximal portion having a trigger mechanism (Column 6 lines 40-50), a driver/torque subassembly in the outer tube and movable relative to the outer tube (Figure 11 Element 42), and at least a pair of resilient force transmitting arms/protruding arms (Fig 11a, arms 48).

Regarding Claim 16: Gotfried teaches an outer tube/shaft having a crenulated tip (Figure 11 Element 44).

Regarding Claim 19: Gotfried teaches an outer tube being biased to a distally advanced position (Figure 11 Element 47).

Regarding Claim 20: Gotfried teaches a pilot disposed within the outer tube, having a tapered surface (Figure 11 Element 41).

Regarding Claim 21: Gotfried teaches an instrument comprising a fastener retainer (Figure 11 Element 43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al (US PGPub 2003/0158555) in view of Fitts et al (US Pat 6096060).

Sanders et al disclose the claimed invention except for the body portion of the fastener including a center shaft which is tapered. Fitts et al. disclose a shaft that can be tapered (Col 4 Lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the tapered shaft of Fitts et al. in Sanders et al.'s fastener to offer an equivalent means of fitting a tapered screw, tap, or guide into the shaft.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. (US PGPub 2003/0158555).

Sanders et al. disclose the claimed invention except for the height of the head portion being 1.5mm nor a length of a body portion of 5 mm. It would have been obvious to one skill in the art at the time the invention was made to construct the system of Sanders et al. with the height of the head portion being 1.5mm nor a length of a body portion of 5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). The motivation would have been to offer the optimal sizes for patients (using a smaller screw size for a child, for instance). Please see MPEP § 2144.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al (US PGPub 2003/0158555) in view of Gotried et al (US Pat 5429641).

Sanders discloses the claimed invention except for a method of tapping the target tissue with a pilot and installing the fastener by applying linear and rotational force on the head portion.

Gotfried et al. disclose the steps of tapping the bone/tissue using a guide/pilot, and installing the fastener by applying linear and rotational force on the head portion (Col 6 Lines 33-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the steps provided in Gotfried et al. with Sanders et al.'s device to offer an alternative means of implanting the fastener.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US Pat 5429641).

Gotfried discloses a similar device as described in the rejections above. Gotfried does not teach a trigger mechanism that comprises a ratchet mechanism. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use a ratchet mechanism in Gotfried's device. Official Notice is taken that a ratchet mechanism could be used in Gotfried's instrument as an equivalent and alternative means of inserting the absorbable screw fastener.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US Pat 5429641) in view of Sanders et al (US PGPub 2003/0158555).

Gotfried teaches an instrument having an outer tube on a distal end and a trigger mechanism (Figure 11 Elements 47, 48, and 50). Gotfried does not teach an absorbable screw fastener.

However, Sanders et al. teach an absorbable screw fastener/surgical screw system having a body portion/shank and a head portion (Paragraph 29). Gotfried and Sanders et al. are analogous art because they are from the same field of endeavor of orthopedic devices. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Sanders et al.'s screw fastener with Gotfried's instrument. The motivation would have been to offer an alternative and equivalent means of having both the inserter instrument and the screw fastener configured to fit together.

Regarding Claim 25: Gotfried teaches the above claimed invention except for an absorbable screw fastener with a slot extending the entire length thereof.

Sanders et al. teach a fastener where the slot/bore (Figure 1c Element 7) extends the entire length of the screw fastener. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the screw fastener of Sanders et al. in Gotfried's device to offer an alternative means of enabling the surgeon to insert a tool into the slot.

Regarding Claim 26: Gotfried teaches the above claimed invention except for a screw fastener formed of PGA.

Sanders et al. teach a device where the fastener is formed of PGA/PLA and PGA (Paragraphs 37, 39 and 41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the material of Sanders et al. in Gotfried's device to offer an alternative means of biocompatibility between the screw and the patient's body.

Regarding Claim 27: Gotfried teaches the above claimed invention except for the distal end of the body portion defining a distal surface which is angled with respect to the longitudinal axis.

Sanders et al. teach a distal end of the body portion/shank defining a distal surface that is angled with respect to the longitudinal axis (Figure 1a). it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the angled surface of Sanders et al. in Gotfried's invention as an alternative means of inserting the fastener.

Regarding Claim 29: Gotfried teaches the above claimed invention except for a screw faster that has a head portion defining a distal surface which is angled with respect to the longitudinal axis.

Sanders et al. teach a head portion that defines a distal surface that is angled with respect to the longitudinal axis (Figure 1b Element 6a). it would have been obvious to one having ordinary skill in the art at the time the invention was made to offer an alternative means of fitting a tool to the head portion of the fastener.

Regarding Claim 32: Gotfried teaches the above claimed invention except for a a screw fastener having a slot formed in each thread that includes a radiused leading edge and a radiused trailing edge.

Sanders et al. teach a slot formed in each thread that includes at least one of a radiused leading edge and a radiused trailing edge (Figure 1a Element 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to as an alternative means of ensuring the fastener stays in place once inserted.

Regarding Claims 28, 30, and 31: Gotfried teaches the above claimed invention except for a screw fastener having a distal body portion angled at 5 to 15 degrees, a head portion angled at 5 to 15 degrees, and a distal end of a body portion angled at 5 to 15 degrees.

Sanders et al. teach the screw fastener, however Sanders et al. does not teach angle measurements for the head portion or body portion of the fastener. At the time of the invention, it would have been obvious to one having ordinary skill in the art to construct these angle measurements in Sanders et al.'s device with respect to the longitudinal axis to be between 5 and 15 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

With regard to Applicant's argument that Sanders et al. does not disclose a head portion having a driver receiving structure formed in an outer radial surface thereof, an alternate embodiment shows a driver-receiving structure that is formed in an outer radial surface.

With regard to Applicant's argument that claims 25-27, 29 and 32 can not inherently be anticipated, the Examiner agrees with the Applicant.

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With regard to Applicant's argument that Gotfried does not teach an instrument capable of holding a plurality of absorbable fasteners, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Gotfried teaches an instrument that has the relevant structural limitations, and is *able*, if one so desired, to hold a plurality of absorbable fasteners.

With regard to Applicant's argument that Gotfried fails to teach arms that retain and transmit an absorbable screw both axially and rotationally, Gotfried teaches arms that are *capable* of retaining and transmitting a screw both axially (since axial is defined by pertaining to an axis, in this case the axis along screw 41 in Figure 11a) and rotationally.

With regard to Applicant's argument that neither Gotfried nor Sanders teach a driver/torque assembly having a plurality of resilient force transmitting arms, please see the response to arguments above and the rejections above.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexis M. Wistermayer whose telephone number is 571-270-3304. The examiner can normally be reached on Monday - Friday 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. W./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733